

1. Introduction

The Environmental Protection Agency's (EPA) regulation, 40 CFR part 194, sets forth criteria for determining if the Waste Isolation Pilot Plant (WIPP) will comply with EPA's environmental radiation protection standards for the disposal of radioactive waste, found at 40 CFR part 191 subparts B and C. If the Administrator of EPA determines that the WIPP will comply with the standards for disposal, then the Administrator will issue to the Secretary of Energy a certification of compliance which will allow the emplacement of transuranic waste in the WIPP to begin, provided that all other statutory requirements have been met. If a certification is issued, EPA will also use 40 CFR part 194 to determine if the WIPP has remained in compliance with EPA's environmental radiation protection standards, once every five years after the initial receipt of waste for disposal at the WIPP. The final preamble and regulation to 40 CFR part 194, as they appear in the Federal Register, take precedence over any descriptions or interpretations of the final rule that appear in this document.

This document provides much of the necessary background information and technical analyses which the Agency used during the development of 40 CFR part 194. The document explicates fourteen issues considered by EPA in establishing the individual criteria contained in 40 CFR part 194.

1.1 EPA'S REGULATORY OVERSIGHT OF THE WIPP

1.1.1 Purpose of 40 CFR Part 194

The criteria for compliance, 40 CFR part 194, implement the Environmental Protection Agency's (EPA) environmental radiation protection standards, 40 CFR part 191, by applying them to the proposed disposal of transuranic radioactive waste in the Waste Isolation Pilot Plant (WIPP). The EPA previously promulgated 40 CFR part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," to provide standards that will apply to all sites (except Yucca Mountain) for the deep geologic disposal of highly radioactive waste. Complete descriptions of 40 CFR part 191 were published in the *Federal Register* in 1985 (50 Fed. Reg. 38066-38089, Sep. 19, 1985) and 1993 (58 Fed. Reg. 66398 - 66416, Dec. 20, 1993). The WIPP is subject to 40 CFR part 191, and is being constructed by the Department of Energy (DOE) near Carlsbad, New Mexico as a potential repository for the safe disposal of transuranic radioactive waste. The EPA is required by the WIPP Land

Withdrawal Act of 1992 (Pub. L. 102-579) to evaluate whether the WIPP will comply with subparts B and C of 40 CFR part 191 -- known as the "disposal regulations" -- and to issue or deny a certification of compliance. The Department of Energy is required to submit an application to EPA that will be the basis of EPA's evaluation of whether a certification of the WIPP's compliance with the disposal regulations should be issued. The Department of Energy may not begin to emplace transuranic waste underground for disposal at the WIPP until such time as a certification of compliance has been issued and all other requirements of section 7(b) of the WIPP Land Withdrawal Act have been satisfied. With 40 CFR part 194, the Agency establishes criteria by which to judge whether the WIPP is in compliance with the "disposal regulations" and sets forth procedural requirements for this determination.

The criteria for compliance, 40 CFR part 194, also apply to the periodic re-certification of the WIPP's compliance with the disposal regulations. The process of periodic re-certification, established by section 8(f) of the WIPP Land Withdrawal Act, calls for EPA to determine whether the WIPP continues to be in compliance with the disposal regulations, assuming that an initial certification of compliance has been issued. The Secretary of Energy must submit to the Administrator of EPA documentation of the WIPP's continued compliance with the disposal regulations, every five years after the initial receipt of transuranic waste for disposal at the WIPP, until the end of the decommissioning phase. The Agency will use the criteria in determining whether or not the WIPP will have continued to be in compliance.

The WIPP was authorized in 1980 under section 213 of the Department of Energy National Security and Military Applications of the Nuclear Energy Authorization Act of 1980 (Pub. L. 96-164, 93 Stat. 1259, 1265), "for the express purpose of providing a research and development facility to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States." The waste proposed for disposal in the WIPP, transuranic radioactive waste (TRU waste), is waste consisting of materials such as rags, equipment, tools, protective gear and sludges which have become contaminated during atomic energy defense activities. The WIPP Land Withdrawal Act defines transuranic waste to be waste containing more than 100 nano-curies per gram of alpha-emitting radio-isotopes, with half-lives greater than twenty years and atomic number greater than 92, per gram of waste. The Act further stipulates that radioactive waste shall not be transuranic waste if such waste also meets the definition of high-level radioactive waste, has been specifically exempted from the disposal regulations with the concurrence of the Administrator, or has been approved for an alternate method of disposal by the Nuclear Regulatory Commission. The radioactive component of transuranic waste consists of man-made elements created

during the process of nuclear fission, chiefly isotopes of plutonium.

1.1.2 Overview of 40 CFR part 194

The regulation, 40 CFR part 194, sets forth the criteria against which the WIPP's compliance with the disposal regulations of 40 CFR part 191 will be evaluated and is divided into four subparts, consisting of:

- 1) Subpart A, which specifies the protocols for submission of certification applications, the terms of any certification, and the process for any subsequent suspension, modification, or revocation of compliance status.
- 2) Subpart B, which outlines the information to be included with compliance applications to ensure that EPA has adequate information to evaluate the basis for any demonstration of compliance. Subsequent applications for continued compliance must note any changes in such information that have occurred since the previous certification.
- 3) Subpart C, which implements the specific containment, assurance, individual, and groundwater protection requirements of the disposal regulations at 40 CFR part 191. General requirements, such as those for quality assurance and waste characterization, are included to ensure that compliance applications are based on reliable information; they also allow EPA inspection authority to confirm conditions reported in applications. Assessments of disposal system performance are expressed to show the likelihood of release or exposure occurring. Performance assessments for releases must account for the frequency and consequences of potential human intrusion into the repository over the 10,000-year regulatory time frame, as specified by 40 CFR part 194. Assurance requirements, designed to increase confidence in the performance of the disposal system, include criteria for monitoring of repository performance, and implementation of engineered barriers to protect against releases from the disposal system.
- 4) Subpart D, which provides opportunities for public participation in the rulemaking processes for initial certification of compliance and for modification or revocation of any certification. It also provides for public input at critical junctures in the re-certification process. The subpart specifies criteria for notification of the public at each stage of rulemakings, holding of public hearings, opportunity for public comment, and creation and maintenance of public dockets in Washington, DC, and New Mexico.

1.1.3 Statutory and Regulatory Basis

40 CFR part 194 was mandated by Congress in section 8(c) of the WIPP Land Withdrawal Act. The criteria promulgated in 40 CFR part 194 implement only those subparts of 40 CFR part 191 that apply to the disposal of transuranic radioactive waste. 40 CFR part 194 does not amend 40 CFR part 191. Subpart A of 40 CFR part 191 applies to the management of spent nuclear fuel, high-level and transuranic radioactive wastes at sites designated for the disposal of these wastes and is not the subject of 40 CFR part 194. However, section 9(a) of the WIPP Land Withdrawal Act stipulates that the Secretary of Energy shall comply with respect to the WIPP with Subpart A of 40 CFR part 191. With the Energy Policy Act of 1992, Congress mandated the development of regulations to replace 40 CFR part 191 for the Yucca Mountain site only, but the entire standard, 40 CFR part 191, remains applicable to the WIPP. See 106 Stat. 2921, section 801(a)(1). The entire 40 CFR part 191 standard was developed to establish generally applicable standards for the protection of the general environment from radioactive materials, specifically those disposed of in mined geologic repositories. The standard was developed pursuant to the Agency's authorities under the Atomic Energy Act (AEA) of 1954, as amended, and Reorganization Plan No. 3 of 1970 (NIX70). A more complete description of the development of 40 CFR part 191 may be found later in this chapter.

1.1.4 Compliance with Other Environmental Laws and Regulations

The WIPP is regulated under the Resource Conservation and Recovery Act (RCRA) and is subject to both the Part B licensing requirements and the land disposal restrictions of that statute. The WIPP must comply with other environmental laws, including, among other statutes, the Clean Air Act (40 U.S.C. 7401 et seq), the Toxic Substances Control Act (15 U.S.C. 2601 et seq) and the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 et seq). The promulgation of 40 CFR part 194 does not affect the need for DOE to comply with these and all other applicable environmental laws with respect to the WIPP.

Much of the waste proposed for disposal in the WIPP is mixed waste, i.e., waste composed of both radioactive and hazardous constituents, the latter's disposal being controlled by the regulations set forth under RCRA. As mandated by section 7(a) of the WIPP Land Withdrawal Act, the Secretary of Energy must obtain from the Administrator a determination

of no-migration under the land disposal restrictions of RCRA, prior to commencing the emplacement of waste in the WIPP. A conditional no-migration determination for the now withdrawn test phase was granted by EPA on November 14, 1990. This conditional determination must be amended and formal approval granted before disposal of radioactive waste can begin.

1.2 HISTORY OF U.S. POLICY ON GEOLOGIC DISPOSAL

Since the 1940s, the Federal Government has assumed ultimate responsibility for the care and disposal of high-level radioactive wastes, regardless of whether they are produced by commercial or national defense activities. To respond to this need, in 1949 the Atomic Energy Commission (AEC) initiated research and development work on the conversion of high-level radioactive liquid wastes into a stable, solid form. Then, in 1955, at the request of the AEC, a National Academy of Sciences - National Research Council (NAS-NRC) Advisory Committee was established to consider the disposal of high-level radioactive wastes within the United States. Its report (NAS57), issued in 1957, recommended the following:

1. The AEC continue to develop processes for the solidification of high-level radioactive liquid wastes, and
2. Naturally occurring salt formations are the most promising medium for the long-term isolation of these solidified wastes.

Project Salt Vault, conducted from 1965 to 1967 by the AEC in an abandoned salt mine near Lyons, Kansas, was initiated to demonstrate the safety and feasibility of handling and storing solid wastes in salt formations (MCC70).

In 1968, the AEC again asked the NAS-NRC to establish a Committee on Radioactive Waste Management (CRWM) to advise the AEC concerning its long-range radioactive waste management plans and to evaluate the feasibility of disposing of solidified radioactive wastes in bedded salt. The CRWM convened a panel to discuss the disposal of radioactive wastes in salt mines. Based on the recommendations of the panel, the CRWM concluded that bedded salt is satisfactory for the disposal of radioactive wastes (NAS70).

In 1970, the AEC announced the tentative selection of a site at Lyons, Kansas, for the establishment of a national radioactive waste repository (AEC70). During the next two years,

however, in-depth site studies raised several questions concerning the safe plugging of old exploratory wells and on proposals for expanded salt mining activities. These questions and growing public opposition to the Lyons site prompted the AEC in late 1971 to pursue alternatives (DOU72).

The Federal Government intensified its program to develop and demonstrate a permanent disposal method for high-level radioactive wastes and the Office of Management and Budget (OMB) established an interagency task force on commercial wastes in March, 1976. The OMB interagency task force defined the responsibility of each Federal agency involved in high-level waste management, including the preparation of environmental standards for high-level wastes by EPA (LYN76, ENG77a, ENG77b).

A status report on the management of commercial radioactive nuclear wastes, published in May 1976 by the President's Federal Energy Resources Council (FERC), emphasized the need for coordination of administration policies and programs relating to energy. The FERC established a nuclear subcommittee to coordinate Federal nuclear policy and programs to assure an integrated government effort. This report called for an accelerated, comprehensive government radioactive waste program plan and recommended the formation of an interagency task force to coordinate activities among the responsible Federal agencies. EPA was given the responsibility for establishing general environmental standards governing waste disposal activities (FER76).

In 1976, President Ford issued a major policy statement on nuclear waste. As part of his comprehensive statement, he announced new steps to assure that the United States would have facilities for the long-term management of nuclear waste from commercial power plants. The President's actions were based on the findings of the OMB interagency task force formed in March 1976. He announced that the experts had concluded that the most practical method for disposing of high-level radioactive wastes is in geologic repositories located in stable formations deep underground. EPA's responsibilities were better defined to include issuing general environmental standards governing nuclear waste facility releases to the biosphere above natural background radiation levels (FOR76). These standards were to place a numerical limit on long-term radiation releases outside the boundary of the repository.

In December 1976, EPA announced its intent to develop environmental radiation protection criteria for radioactive wastes to assure the protection of public health and the general environment (EPA76). These efforts resulted in a series of radioactive waste disposal workshops, held in 1977 and 1978 (EPA77a, EPA77b, EPA78a, EPA78b).

In 1978, President Carter established the Interagency Review Group (IRG) to recommend an administrative policy for addressing the long-term management of nuclear waste. The IRG was to recommend programs that would support the policy when adopted. The IRG report re-emphasized EPA's role in developing generally applicable standards for the disposal of high-level wastes, spent nuclear fuel, and transuranic wastes (DOE79). In a message to Congress on February 12, 1980, the President outlined the content of a comprehensive national radioactive waste management program based on the IRG recommendations. The message called for an interim strategy for disposal of high-level and transuranic wastes that would rely on mined geologic repositories. The message repeated that EPA was responsible for creating general criteria and numerical standards for nuclear waste management activities (CAR80).

1.2.1 EPA's Development of the Generally Applicable 40 CFR part 191

In November 1978, EPA published proposed "Criteria for Radioactive Wastes," which were intended as Federal Guidance for storage and disposal of all forms of radioactive wastes (EPA78c). In March 1981, however, EPA withdrew the proposed criteria because the many different types of radioactive wastes made the issuance of generic disposal guidance too problematic (EPA81).

In 1982, under the authority of the Atomic Energy Act of 1954, EPA proposed a set of standards under 40 CFR part 191, "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes" (EPA82). Shortly after the publication of EPA's proposed rule, Congress passed the Nuclear Waste Policy Act of 1982, wherein EPA was to "...promulgate generally applicable standards for the protection of the general environment from off-site releases from radioactive material in repositories..." not later than January 1984 (NWP83).

After the first comment period on the proposed rule ended on May 2, 1983, EPA held two public hearings on the proposed standards--one in Washington, D.C., on May 12-14, 1983, and one in Denver, CO, on May 19-21, 1983--and during a second public comment period

requested post-hearing comments (EPA83a, EPA83b). More than 200 comment letters were received during these two comment periods, and 13 oral statements were made at the public hearings. Responses to comments received from the public were subsequently published and released in August 1985 (EPA85a).

In parallel with its public review and comment effort, the Agency conducted an independent scientific review of the technical basis for the proposed 40 CFR part 191 standards through a special Subcommittee of the Agency's Science Advisory Board (SAB). The Subcommittee held nine public meetings from January 18, 1983, through September 21, 1983, and later prepared and released a final report on February 17, 1984 (EPA83c, SAB84). The SAB review found that the Agency's analyses in support of the proposed standards were comprehensive and scientifically competent, but contained several recommendations for improvement. The report was publicly released on May 8, 1984, and the public was requested to comment on the findings and recommendations (EPA84). Public responses to the SAB report were subsequently presented and released in August 1985 (EPA85b).

On February 8, 1985, the Natural Resources Defense Council, the Environmental Defense Fund, the Environmental Policy Institute, the Sierra Club, and the Snake River Alliance brought suit against the Agency and the Administrator because they had failed to comply with the January 7, 1984, deadline mandated by the NWPA for promulgation of the standards. A consent order was negotiated with the plaintiffs that required the standards to be promulgated on or before August 15, 1985. EPA issued the final rule under 40 CFR part 191 on that date (EPA85c, EPA85d, EPA85e).

EPA standards were divided into two main sections, Subparts A and B. Subpart A addressed the management and storage of waste. For any disposal facility operated by DOE and not regulated by the Nuclear Regulatory Commission (NRC) or by Agreement States, under Subpart A of the standard, the exposure limits to any member of the general public were 25 millirem (mrem) to the whole body and 75 mrem to any critical organ. For facilities regulated by the Nuclear Regulatory Commission or Agreement States, the standards adopt the annual dose limits given in 40 CFR part 190, the environmental standards for the uranium fuel cycle: 25 mrem to the whole body, 75 mrem to the thyroid, and 25 mrem to the critical organ.

Subpart B imposed limits on the release of radioactive materials into the environment following closure of the repository. The key provisions of Subpart B were:

- Limits on cumulative releases of radioactive materials into the environment over 10,000 years;
- Assurance requirements to compensate for uncertainties in achieving the desired level of protection;
- Individual exposure limits based on the consumption of groundwater and any other potential exposure pathways for 1,000 years after disposal; and
- Groundwater protection requirements in terms of allowable radionuclide concentrations and associated doses for 1,000 years after disposal.

§191.15 and §191.16 of Subpart B limited the annual dose to any member of the general public to 25 mrem to the whole body and 75 mrem to any critical organ. The groundwater concentration for beta or gamma emitters was limited to the equivalent yearly whole body or organ dose of 4 mrem. The allowable water concentration for alpha emitters (including radium-226 and radium-228, but excluding radon) was 15 picocuries/liter. For radium-226 and radium-228 alone, the concentration limit was 5 picocuries/liter. Appendix A of the standards provided cumulative release limits for other radionuclides.

In March 1986, five environmental groups, led by the Natural Resources Defense Council, and four States filed petitions for a review of 40 CFR part 191 (USC87). These suits were consolidated and argued in the U.S. Court of Appeals for the First Circuit in Boston. The main challenges concerned:

1. Violation of the Safe Drinking Water Act (SDWA) underground injection requirements;
2. Inadequate notice and comment opportunity on the groundwater protection requirements; and
3. Arbitrary standards, not supported in the record or not adequately explained.

In July 1987, the Court rendered its opinion and noted three findings against the Agency and two favorable judgments. The Court's action resulted in the remand of the standards. The Court began by looking at the definition of "underground injection," which is the "subsurface emplacement of fluids by well injection." A "well" is defined by the SDWA and EPA as a shaft "bored, drilled, or driven where the depth is greater than the largest surface dimension." A "fluid" is a material or substance that flows or moves whether in a semi-solid, sludge, gas, or any other form or state." In the view of the Court, the method envisioned by DOE for disposal of radioactive wastes in underground repositories might fit both of the latter definitions and would "likely constitute an underground injection under the SDWA."

Under the SDWA, the Agency is required to assure that underground sources of drinking water will not be endangered by any underground injection. With regard to such potential endangerment, the Court supported part, but not all, of the Agency's approach. A dichotomy appeared when endangerment was considered inside the "controlled area" versus beyond the controlled area (i.e., in the accessible environment). Inside the controlled area, the Court ruled that endangerment of groundwater was permitted. Therefore, EPA's approach of using the geological formation as part of the containment was valid. However, outside the controlled area where endangerment would not be permitted, the Court found that §191.15 as promulgated would endanger drinking water supplies. In the context of the SDWA, "endangerment" occurs when doses are higher than that allowed by the Primary Drinking Water Regulations. §191.15 permits an annual dose of 25 mrem to the whole body and 75 mrem to any critical organ from all pathways. On the other hand, the regulations under the SDWA allow only 4 mrem doses from drinking water. The Court recognized that less than 4 mrem may result from the groundwater pathway; however, it rejected this possibility because the Agency stated that radioactivity may eventually be released into the groundwater system near the repository which could result in substantially higher doses. Therefore, the Court decided that a large fraction of the 25 mrem could be received through the groundwater exposure pathway. Accordingly, the Court found that the high-level waste standards should have been consistent with the SDWA, or the Agency should have explained that a different standard was adopted and justified its position.

The Court also noted that the Agency was not incorrect in promulgating the proposed standards, but that the Agency neither acknowledged the interrelationship of the SDWA and HLW rules, nor did it adequately explain the divergence between them. The Court also supported the petitioner's argument that the Agency arbitrarily selected the 1,000-year limit

for individual protection requirements (§191.15) under undisturbed performance. The Court indicated that the 1,000-year criterion is not inherently flawed, but the administrative record and the Agency's explanations did not adequately support this choice. The criterion was remanded for reconsideration and a more thorough explanation for its basis. Finally, the Court found that the Agency did not provide adequate opportunity for notice and comments on §191.16 (Groundwater Protection Requirements), which was added to Subpart B after the standards were proposed. This section was remanded for a second notice and comment opportunity.

In August 1987, the Justice Department petitioned the First Circuit Court to reinstate all of 40 CFR part 191 except for §191.15 and §191.16, which were originally found defective. The Natural Resources Defense Council filed an opposing opinion. In response, the Court issued an Amended Decree that reinstated Subpart A, but continued the remand of Subpart B.

On October 30, 1992, the President signed the WIPP LWA. This Act reinstated Subpart B of 40 CFR part 191, except §191.15 and §191.16, and required the Administrator to issue final disposal standards. The reinstatement of these regulations does not apply to the characterization, licensing, construction, operation, or closure of any site required to be characterized under the NWPA Section 113(a) of Public Law 97-425. On December 20, 1993, EPA issued amendments to 40 CFR part 191 which: eliminated §191.16 of the original rule; altered the individual protection requirements; and added Subpart C on groundwater protection. The amended standards represent the Agency's response to the above legislation and to the issues raised by the court pertaining to individual and groundwater requirements. EPA did not revisit any of the regulations reinstated by the WIPP LWA.

1.3 PURPOSE AND SCOPE OF THE BACKGROUND INFORMATION DOCUMENT

This Background Information Document (BID) provides much of the necessary background information and technical analyses which support the Agency's development of 40 CFR part 194. The BID explicates fourteen issues considered by EPA in establishing the individual criteria contained in 40 CFR part 194. For clarity of presentation, the issues generally have been arranged to correspond to their relative placement in 40 CFR part 194. Following are brief descriptions of the remaining chapters:

GENERAL REQUIREMENTS

- Chapter 2 - An assessment of the DOE Quality Assurance (QA) program as it relates to site characterization, data gathering, data analysis, and data modeling

at the WIPP. DOE, EPA, NRC, and other QA guidance are examined.

- Chapter 3 - A discussion of the use of appropriate models in the WIPP performance assessment.
- Chapter 4 - A review of the DOE TRU waste characterization program.
- Chapter 5 - A review of background information and technical analyses relevant to future state assumptions.
- Chapter 6 - A discussion of the formal use of expert judgment in scientific investigation and how the technique has been applied at the WIPP.
- Chapter 7 - A review of peer review procedures and a discussion of their application in the WIPP assessments.

CONTAINMENT REQUIREMENTS

- Chapter 8 - A discussion of background information on evaluation of uncertainty, and a summary of regulatory approaches for dealing with uncertainty, including "reasonable expectation."
- Chapter 9 - A discussion of resource drilling and mining.

ASSURANCE REQUIREMENTS

- Chapter 10 - A discussion of regulatory requirements relevant to active institutional controls at the WIPP and DOE proposed action.
- Chapter 11 - A review of issues relevant to monitoring, including the necessity for monitoring and potential techniques for pre- and post-disposal monitoring.
- Chapter 12 - A discussion on the use of passive institutional controls, including permanent markers, public records and archives, and government ownership and regulations.
- Chapter 13 - A review of the regulations concerning engineered barriers and consideration of engineered barriers at the WIPP.
- Chapter 14 - A discussion on the development of compliance criteria for individual and groundwater protection requirements.

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